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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,861	06/24/2003	Kenneth Walter Locke	215233-00400	7200

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EXAMINER

OH, TAYLOR V

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/601,861

Applicant(s)

LOCKE ET AL.

Examiner

Taylor Victor Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/10/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Final Rejection

The Status of Claims

Claims 1, 4-6, and 9-10 are pending.

Claims 1, 4-6, and 9-10 have been rejected.

Claim Rejections - 35 USC § 112

1. Applicants' argument filed 2/22/05 have been fully considered but they are not persuasive.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 1, 4-6, and 9-10 under 35 U.S.C. 112, second paragraph, has been maintained due to applicants' failure to modify the claims in the amendment.

Claims 4 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 4 and 9, the phrase "polymorphic forms B and C about $9^{\circ} 2\text{-theta}$ " is recited. This expression is vague and indefinite. The specific PXRD patterns of

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polymorphic forms B and C are needed to identify each of the specific crystalline Forms B and C which are uniquely different from the other polymorphic form by reciting their corresponding X-ray diffraction values because the x-ray pattern of a pure crystalline substance can be considered as a "fingerprint" with each crystalline material having within limits, a unique diffraction pattern; furthermore, there are other characteristics to be used in order to distinguish each of the polymorphic Forms B and C further from the other polymorphic forms, such as bioavailability, solubility, dissolution rate, chemical and physical stability, melting point, color, filterability, density, and flow properties. In addition, the polymorphs are further characterized by other analytical techniques such as differential scanning calorimetry, hot stage optical microscopy, and Raman and infrared spectroscopy. The above techniques are essential tools to be used for identifying each of the "polymorphic Forms B and C" clearly; and it is up to applicants to select which critical parameters may be used so as to establish the unique "polymorphic Forms B and C."

Applicants' Argument

2. Applicants argue the following issues:
 - a. Since a PXRD spectrum may be considered a fingerprint of the desired compound, Figure 6 of the specification containing the fingerprints of form A, B, C allows the skilled artisan in the art to readily identify these different crystal products using PXRD analysis.

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Applicants' arguments have been noted, but the arguments are not persuasive.

First, regarding applicant's arguments, the Examiner has noted applicants' argument. However, in claims 1, 4, and 9, each of the polymorphic forms A, B, and C are clearly not identified because there are no their corresponding X-ray diffraction values for each of them in the claims; this does lead to the ambiguity of the claims as a whole.

Moreover, the second paragraph of 35 USC 112 requires that the claims particularly point out the subject matter that applicants regard as the invention. A claim referring to the specification is improper. Ex parte Fressola, 27 U.S.P.Q. 2d 1608 (U.S. Pat. & Trademark Bd. Pat. App. & Int 1993).

Therefore, the rejection under second paragraph of 35 USC 112 is still applicable to the claimed invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Taylor V Oh
5/16/05

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